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March 25, 2025

VIA CM/ECF

The Honorable Richard G. Andrews
United States District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

**Re: *In re Entresto (Sacubitril/Valsartan) Patent Litigation,*
C.A. Nos. 20-md-2930-RGA & 19-2053-RGA**

Dear Judge Andrews,

We write on behalf of Plaintiff Novartis Pharmaceuticals Corporation in these matters regarding entry of a proposed final judgment concerning U.S. Patent No. 8,101,659 (the “’659 Patent”). As requested by the Court, on February 6, 2025, Novartis and MSN each submitted proposed orders for entry of final judgment (*see* D.I. 1763 (Novartis) and D.I. 1762 (MSN) in C.A. 20-md-2930), and then submitted briefing in support of their respective proposed final judgments on February 7, 2025 (*see* D.I. 1765, 1766).

Earlier today, the Federal Circuit denied MSN’s petition for panel rehearing or rehearing en banc with respect to the ’659 Patent, and also denied MSN’s request to reconsider the Federal Circuit’s January 21 injunction order. Thus, left in place is the Circuit’s order enjoining MSN “until issuance of the mandate ... from commercial marketing and sale of their generic version of Entresto®”. Based on general timelines and under the Federal Circuit’s standard procedures, the Federal Circuit will likely issue the mandate on or before April 1, 2025.

Because the Federal Circuit has denied rehearing and maintained its decision upholding validity of the ’659 Patent, a final judgment and injunction against MSN is needed from this Court in time to ensure that MSN cannot launch its ANDA product during any gap in time between the issuance of the mandate and entry of the FDA’s reset order.¹ An injunction from this Court

¹ In a separate suit brought by Novartis against MSN for trade dress infringement in the United States District Court for the District of New Jersey, that court on March 17, 2025 preliminarily enjoined MSN “from manufacturing, producing, distributing, circulating, selling, marketing, offering for sale, advertising, promoting, or displaying the MSN Drug, in a manner likely to infringe on [Novartis’s] trade dress.” Exhibit A hereto. That preliminary injunction, however, does not alleviate the need for injunctive relief from this Court because MSN has moved to stay the preliminary injunction and has appealed the preliminary injunction to the Third Circuit, and

would preserve the relief the Federal Circuit ordered in granting and maintaining an appellate injunction until issuance of the mandate.

Novartis respectfully submits this letter to seek clarity as soon as possible from the Court regarding: (1) the language of the anticipated final judgment and any injunctive relief; and (2) the timing of the Court's anticipated entry of final judgment and any injunctive relief following the issuance of the mandate. Novartis respectfully submits that such clarity is necessary in order to avoid burdening this Court or the Federal Circuit with further motion practice.

Counsel are available at the Court's convenience.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

cc: Counsel of Record (via Electronic Mail)

thus the preliminary injunction could be stayed or lifted at any time. MSN further has represented to the New Jersey Court that "MSN is otherwise poised to launch its drug when the Federal Circuit issues its mandate in the related pending patent litigation." Exhibit B hereto.